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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/759,222
Filing Date: January 20, 2004
Appellant(s): MEHLHORN, ROLF JOACHIM

Bernard F. Rose
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 30, 2009 appealing from the Office action mailed March 31, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

The grounds of rejection that is missing is claims 16-23 rejected under the ground of nonstatutory obviousness-type double patenting over claims 1-7 of U.S. Patent No. 5,762,957 (Obviousness-Type Double Patenting Rejection).

The grounds of rejection that claims 1-8, 10-12 and 16-23 contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, has

possession of the claimed invention (Written Description Rejection) is hereby withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,762,957 MEHLHORN 6-1998

Deamer et al., "The Response of Fluorescent Amines to pH Gradients Across Liposome Membranes", Biochimica et Biophysica Acta, Vol. 274, pps. 323-335 (1972).

Nichols et al., "Catecholamine Uptake and Concentration by Liposomes Maintaining pH Gradients", Biochimica et Biophysica Acta, Vol. 455, pps. 269-271 (1976).

Cramer et al., "NMR Studies of pH-Induced Transport of Carboxylic Acids Across Phospholipid Vesicle Membranes", Biochemical and Biophysical Research Communications, Vol. 75, No. 2, pps. 295-301 (1997).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,762,957. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the present claims and the patented claims lie in that the present claims, an additional step is applied with the kit.

The present claims would anticipate the patented claims because the patented claims recite "comprising" and thus opens the claims to the inclusion of addition steps.

Claims 16-23 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. or Deamer et al. or Cramer et al.

Nichols et al. teach a method of preparation of liposomes using instant method (note the entire publication, page 270 in particular). The drugs loaded include epinephrine (page 271). The method involves preparing liposomes with acidic pH and titrating them with a base to create a pH gradient and adding a basic drug such as epinephrine to load the drug.

Deamer et al. teach a method of preparation of liposomes using instant method (note the entire publication). The compounds loaded include amines (note abstract and Method section). The method involves preparing liposomes with acidic pH and titrating them with a base to create pH gradient and adding a basic amine.

Cramer et al. teach a method of loading substance using pH gradient (note the abstract). The method involves the preparation of liposomes and lowering the pH of the external medium. The compounds loaded are acidic in nature (note the abstract and Materials and Methods).

Nichols et al. and Deamer et al. do not teach the establishment of the pH gradient by the addition of an acid. It is deemed, however, to be within the skill of the art of chemistry that if the internal medium is basic one can only establish a gradient by the addition of an acidic substance (that is, altering the pH). Nichols et al. and Deamer et al. teach the concept of loading a chemical species into the liposomes using a pH gradient. It would have been obvious to one of ordinary skill in the art to load any drug with the expectation of similar loading since Nichols et al. and Deamer et al. teach the principle of loading.

Cramer et al. do not teach the establishment of the pH gradient by the addition of an acid. It is deemed, however, to be within in the skill of the art of chemistry that if the internal medium is basic one can only establish a gradient by the addition of an acidic substance (that is, altering the pH). Cramer et al. teach the concept of loading a chemical species into the liposomes using a pH gradient. It would have been obvious to

one of ordinary skill in the art to load any drug with the expectation of similar loading since Cramer et al. teach the principle of loading.

Claims 1-12 are not allowed.

(10) Response to Argument

Applicants' remarks regarding the prior art, each individual reference, do not teach one skilled in the chemistry art to establish a pH gradient when an internal medium is basic, one should add an acid to the external medium are not persuasive since the prior art, Nichols et al., Deamer et al., and Cramer et al., does teach the concept of loading a chemical species into the liposomes using a pH gradient. Again, it would have been obvious to one of ordinary skill in the art to load any drug with the expectation of similar loading since applicants have not demonstrated side-by-side comparison of the prior art's liposome loading versus the present application's liposome loading.

The rejection made under 35 USC 103(a) is adhered to.

Claims 1-12 are not allowed.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/KEVIN WEDDINGTON/

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